# IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA

D.J., TONI CORDOVA, et al.,	)	
Plaintiffs,	)	Civil Action No. 2:22-752
v.	)	CIVII ACTION NO. 2.22-732
UNIVERSITY OF IOWA HOSPITALS and CLINICS, et al.,	)	Judge Cathy Bissoon
Defendants.	)	

# **MEMORANDUM AND ORDER**

### I. MEMORANDUM

For the reasons stated below, the Motion to Dismiss (Doc. 133) Plaintiffs' Second Amended Complaint filed by Defendants Ademola Abiose, Ann & Robert H. Lurie Children's Hospital of Chicago, Maryam Banikazemi, Baylor College of Medicine, Cedars-Sinai Medical Center, Joel Charrow, Children's Memorial Hospital, Cincinnati Children's Hospital, Columbia University Medical Center, Duke University Health Center, Christine Eng, Massachusetts General Hospital, Michael Mauer, Manesh Patel, Ronald Scott, Katherine Sims, University of Alabama at Birmingham Medicine, University of Iowa Hospitals and Clinics, University of Minnesota, University of Washington Medicine, David Warnock, William Wilcox ("Moving Defendants")<sup>1</sup> will be GRANTED.

<sup>&</sup>lt;sup>1</sup> The Moving Defendants include eleven medical centers ("Medical Center Defendants") and their respective physicians ("Physician Defendants"). Four of the Medical Center Defendants – University of Iowa Hospitals and Clinics, University of Minnesota, University of Washington and University of Alabama at Birmingham – are public entities ("Public Entity Defendants"). The only two non-moving Defendants are foreign Defendants, Dominique Germain and the University of Versailles ("Foreign Defendants"). There is no reflection on the docket indicating that the Foreign Defendants have been served.

## A. Background

On September 30, 2023, this Court granted Moving Defendants' Motion to Dismiss Plaintiffs' First Amended Complaint for lack of personal jurisdiction. (Doc. 121). Specifically, the Court held that "there ha[d] been no showing that exercising personal jurisdiction over the Moving Defendants comports with Pennsylvania's long-arm statute or that hauling the Moving Defendants into court in Pennsylvania would be fair, reasonable, or consistent with federal due process standards for specific jurisdiction." Id. at 7–8. In its dismissal order, the Court afforded Plaintiffs the opportunity to file a Second Amended Complaint making last, best efforts to identify a valid jurisdictional basis for proceeding. *See* id. Plaintiffs filed their Second Amended Complaint on October 24, 2023, and have again failed to make that showing. (Doc. 124).

On November 17, 2023, Defendants again moved to dismiss Plaintiffs' Second Amended Complaint under Federal Rule of Civil Procedure 12(b)(2) for lack of personal jurisdiction. (Doc. 133). The Motion to Dismiss additionally seeks dismissal of the claims against the Public Entity Defendants, and their respective physicians, pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(2), based on lack of standing and Eleventh Amendment immunity. Plaintiffs oppose Defendants' Motion. (Doc. 135).

This case is a putative class action brought by sixteen named Plaintiffs on behalf of themselves or their decedents, based on harm allegedly sustained as a result of a shortage of a drug called Fabrazyme that began in 2009 and lasted until 2012. Second Am. Compl. (Doc. 124)

<sup>&</sup>lt;sup>2</sup> As with the First Amended Complaint, Plaintiffs agree that Eleventh Amendment immunity applies to the Public Entity Defendants as to Counts 1-7 of the Second Amended Complaint, and, accordingly, did not name them as defendants as to those counts. Count 8 asserts an Interstate Compact Clause claim against only the Public Entity Defendants and their physicians in their official capacities.

¶¶ 1-16, 83-104. The alleged facts of the case are well known to the parties, and the Court recounts them only briefly here. Plaintiffs and/or their decedents suffered from Fabry disease, a rare, but lethal, heritable, genetic illness, in which a gene for an enzyme required to metabolize a certain fat is mutated or missing, resulting in the build-up of that fat in cells, blood vessels and organs, resulting in inflammation and, ultimately, death. Id. ¶¶ 1-16, 68-70. Fabrazyme is a synthetic version of the enzyme that is infused every two weeks to treat Fabry disease and mitigate its effects. Id. ¶¶ 71-73. Fabrazyme manufacturer, Sanofi Genzyme Corporation, is the sole FDA-approved supplier of enzyme replacement therapy for Fabry disease in the United States market. Id. ¶¶ 77-80.

The Physician Defendants did not treat any of the named Plaintiffs or their decedents; rather, they represented their respective medical institutions as members of the Fabry Stakeholder's Working Group ("FSWG"), a group of experts convened by Sanofi Genzyme to prepare guidance to the Fabry community on the management of Fabrazyme supply during the drug shortage. Id. ¶ 105-129 and Exs. A, B. FWSG prepared two written guidance documents containing recommendations for temporary reductions of Fabrazyme use in light of the shortage. Id. Ex. A (issued in July 2009), Ex. B (issued in or around September 2009). The Second Amended Complaint alleges that the Guidance was disseminated to all Fabry patients and their physicians, nationwide. Id. ¶¶ 116-120. The lawsuit essentially contends that Defendants, through their participation in the FSWG, intentionally initiated a harmful experimental medical protocol on Plaintiffs and collected research data on low-dose Fabrazyme efficacy without Plaintiffs' informed consent.<sup>3</sup>

<sup>&</sup>lt;sup>3</sup> Counts 1-7 assert the following tort and constitutional claims against the non-public entity Defendants: (1) tort of failure to obtain informed consent; (2) breach of fiduciary duty; (3) Equal Protection violation (42 U.S.C. § 1981); (4) violation of 42 U.S.C. § 1983; (5) conspiracy to

# B. 12(b)(2) Motion to Dismiss – Lack of Personal Jurisdiction

Under Federal Rule of Civil Procedure 12(b)(2), the plaintiff has the burden of pleading sufficient facts to establish that the court has personal jurisdiction over the defendants. *See*Pinker v. Roche Holdings, Ltd., 292 F.3d 361, 368 (3d Cir. 2002). When a defendant challenges personal jurisdiction, "the plaintiff must 'prove by affidavits or other competent evidence that jurisdiction is proper." Metcalfe v. Renaissance Marine, Inc., 566 F.3d 324, 330 (3d Cir. 2009) (quoting Dayhoff Inc.v. H.J. Heinz Co., 86 F.3d 1287, 1302 (3d Cir. 1996)). Absent jurisdictional discovery, however, a plaintiff need only "a prima facie case of personal jurisdiction," and is entitled to have the allegations in the complaint taken as true and all factual disputes resolved in plaintiff's favor. Miller Yacht Sales, Inc. v. Smith, 384 F.3d 93, 97 (3d Cir. 2004).

Due process requires a finding of minimum contacts with Pennsylvania such that the exercise of personal jurisdiction "does not offend traditional notions of fair play and substantial justice." O'Connor v. Sandy Lane Hotel Co., 496 F.3d 312, 316-17 (3d Cir. 2007). Personal jurisdiction can be general or specific. *See* <u>id.</u> at 317. Specific jurisdiction typically is analyzed on a "claim by claim basis" and "must arise out of or relate to the defendant's contacts with the forum." <u>Ford Motor Co. v. Mont. Eighth Jud. Dist. Ct.</u>, 141 S. Ct. 1017, 1024 (U.S. 2021); <u>Marten v. Goodwin</u>, 499 F.3d 290, 296 (3d Cir. 2007). To determine specific jurisdiction in this Circuit: (1) the defendant must have "purposefully directed its activities at the forum"; (2) the

deprive rights from citizens (42 U.S.C. § 1985(3)); (6) negligent deprivation of rights of citizens (42 U.S.C. § 1986); and (7) Virginia wrongful death or survival action claims (Va. Code §§ 8.01-50, 8.01-25). Count Eight asserts a claim under the Interstate Compact Clause (U.S. Const., Art. 1, § 10, Cl. 3) against the Public Entity Defendants, and their respective physicians in their official capacities. *See generally* 2d Am. Compl. ¶¶ 288-496.

litigation must "arise out of or relate to" at least one of those activities; and (2) the exercise of jurisdiction otherwise must "comport with fair play and substantial justice." O'Connor, 496 F.3d at 317. In the case of intentional torts, a plaintiff also can establish specific jurisdiction under the Calder "effects test." See Calder v. Jones, 465 U.S. 783 (1984); Marten 499 F.3d at 297. The effects test is met when (1) the defendant committed an intentional tort; (2) the plaintiff felt the brunt of the harm in the forum such that the forum can be said to be the focal point of the harm; and (3) the defendant expressly aimed his conduct at the forum such that the forum can be said to be the focal point of the tortious activity. Marten, 499 F.3d at 297.

The Second Amended Complaint asserts both federal-question and diversity jurisdiction. *See* Compl. ¶¶ 40-41. In diversity cases, the forum state's law governs whether personal jurisdiction exists over an out-of-state defendant. *See* Metcalfe, 566 F.3d at 330. With federal question jurisdiction, the personal jurisdiction analysis lies under the Fifth Amendment's due process clause. *See* Max Daetwyler Corp. v. A.W. German, Corp., 762 F.2d 290, 293 (3d Ci. 1985). Nevertheless, when a pleading asserts claims under federal laws not authorizing nationwide service of process, the court may exercise personal jurisdiction only "to the extent [the defendant] is 'subject to the jurisdiction' of [the forum state's] courts." Fischer v. Fed. Express. Corp., 42 F.4th 366, 382 (3d Cir. 2022). "For a defendant to be subject to the jurisdiction of a state court, the exercise of personal jurisdiction must be [1] authorized by state law, such as by the state's long-arm statute, and [2] must comport with the requirements of the Fourteenth Amendment." Fischer v. Fed. Express Corp., 42 F.4th 366, 382-83 (3d Cir. 2022), cert. denied, 143 S. Ct. 1001 (2023).

Plaintiffs concede that general jurisdiction and nationwide service of process are inapplicable. *See* Pl. Br. Opp. (Doc. 135) at 10. Thus, Plaintiffs must establish specific

jurisdiction under the minimum contacts analysis or the <u>Calder</u> effects test. As noted above, this Plaintiffs again have failed to do.

Here, the Second Amended Complaint does not add significant factual allegations to bolster Plaintiffs' original theories of personal jurisdiction. Rather, Plaintiffs primarily have elaborated on their jurisdictional bases by adding citations to part (a) of Pennsylvania's long-arm statute, 42 Pa. Cons. Stat. Ann. § 5322(a). *See* Pl. Br. Opp. (Doc. 135) at 2-3 ("Specifically, the SAC now recites the statutory language of Pennsylvania Statute § 5322(a)."). The Second Amended Complaint also sets forth Plaintiffs' factual application of the law in block paragraphs following the asserted statutory provisions. *See* id. (citing 2d Am. Compl. ¶¶ 48-54).

Pennsylvania's long-arm statute contains two parts. Subsection (a) contains ten subsections which specify particular types of contact with Pennsylvania that will be deemed sufficient to warrant the exercise of long-arm personal jurisdiction, while Subsection (b) permits the exercise of personal jurisdiction consistent with the Due Process Clause of the Fourteenth Amendment. *See* 42 Pa. Cons. Stat. Ann. § 5322; *see also* Scoggins v. Scoggins, 555 A.2d 1314, 1318–19 (Pa. Super. Ct. 1989). The Second Amended Complaint invokes four of Section 5322(a)'s ten subsections as follows:

- 5322(a)(1)(iii): The shipping of merchandise directly or indirectly into or through the Commonwealth. 2d Am. Compl. ¶ 49;
- 5322(a)(1)(iv): The engaging in any business or profession within this Commonwealth, whether or not such business requires license or approval by any Government unit of this Commonwealth. Id. ¶ 50;
- 5322(a)(2): Contracting to supply services or things in this Commonwealth. <u>Id.</u> ¶ 51;

- 5322 (a)(4): Causing harm or tortious injury in this Commonwealth by an act or omission outside this Commonwealth; and
- 5322(a)(10): Committing any violation within the jurisdiction of this Commonwealth of any statute, home rule charter, local ordinance or resolution, or rule or regulation promulgated there under by any government unit or of any order of court or other government unit. Id. ¶ 53.

What Plaintiffs fail to appreciate, however, is that the Court already conducted a Section 5322 analysis in its Opinion dismissing the First Amended Complaint. *See* Doc. 121 at 7-8 ("In sum, there has been no showing that exercising personal jurisdiction over the Moving Defendants comports with Pennsylvania's long-arm statute or that haling the Moving Defendants into court in Pennsylvania would be fair, reasonable or consistent with federal due process standards for specific jurisdiction."); 42 Pa. Cons. Stat. Ann. § 5322(b).

Although the Court did not analyze each potentially relevant subsection of Section 5322(a), it is well-established that a separate statutory analysis is neither required nor sufficient.

As the Pennsylvania Superior Court aptly explained in <u>Scoggins</u>:

The separate provisions of 42 Pa. C.S.A. § 5322(a)(1–10) set forth various circumstances which the legislature presumed to meet the minimum requisites of due process. Section 5322(b) authorizes long-arm jurisdiction in any other situations where the minimum requisites of due process are met. As a practical matter, each of the ten subsections of § 5322(a) are wholly subsumed within the catchall provision of § 5322(b). Consequently, we find that it is unnecessary and perhaps unwise to enter into a subtle and potentially confusing analysis of the precise scope of any of the subsections of § 5322(a). Rather, the only appropriate focus in cases such as the one *sub judice* is whether the minimum requisites of due process have been met. If they have not been met, the various subsections of § 5322(a) cannot statutorily authorize an unconstitutional exercise of *in personam* jurisdiction. If they have been met, then § 5322(b) authorizes the exercise of *in personam* jurisdiction, and any analysis of the potential applicability of the subsections of § 5322(a) would be superfluous.

Thus, we decline to consider whether § 5322(a)(4) applies to the instant case. "Because our long-arm statute permits the courts of this Commonwealth to exercise personal

jurisdiction over nonresident defendants 'to the fullest extent allowed under the Constitution of the United States,' ..., we need only decide whether holding ... [the nonresident defendant] subject to a suit in Pennsylvania would be a violation of due process."

555 A.2d at 1318–19 (quoting <u>Temtex Products, Inc. v. Kramer</u>, 479 A.2d 500, 505-06 (Pa. Super. Ct. 1984)).

Plaintiffs' argument that a merged analysis misapplies Section 5322 and Pennsylvania's personal jurisdiction jurisprudence is misguided and contrary to the weight of authority. *See*, *e.g.*, Fischer, 42 F.4th at 382-83; Aldossari *ex rel*. Aldossari v. Ripp, 49 F.4th 236, 257 (3d Cir. 2022) (applying Pennsylvania's long-arm statute and reasoning that "[t]he statutory inquiry in this case thus merges with the constitutional one"); Gaboury v. Gaboury, 988 A.2d 672, 679 (Pa. Super. Ct. 2009) (citing Scoggins); Weirbach v. Cellular Connection, LLC, 478 F. Supp. 3d 544, 550 (E.D. Pa. 2020) (under Pennsylvania's long-arm statute, "the inquiry collapses into whether the Court can exercise personal jurisdiction under the 14th Amendment"); 4 Charles A. Wright & Arthur R. Miller, Federal Practice and Procedure § 1069 ("[B]ecause a majority of states . . . have enacted jurisdictional statutes that either have expressly incorporated the due process standard or have been interpreted to extend to the limits of due process, this analysis frequently is collapsed by the federal court into a one-step inquiry: does the assertion of personal jurisdiction satisfy the requirements of due process?").

Here, Plaintiffs' allegations supporting specific jurisdiction as to each count in the First and Second Amended Complaints are identical. *Compare* 1st Am. Compl. ¶¶ 293-325, 345-354, 374-376, 397-399, 416-418, 430-432, *with* 2d Am. Compl. ¶¶ 317-348, 368-377, 397-399, 420-422, 439-441, 453-455. The Court need not undertake a separate statutory analysis to find it lacks specific jurisdiction over the Moving Defendants because, for the same reasons set forth in its prior dismissal order (Doc. 121), the Second Amended Complaint does not satisfy the relevant

constitutional standards. Again, repackaging these allegations under the guise of Section 5322(a) cannot expand this Court's jurisdiction beyond these constitutionally prescribed limits. *See*Scoggins, 555 A.2d at 1318–19; Derman v. Wilair Servs., Inc., 590 A.2d 317, 320 (Pa. Super. Ct. 1991).<sup>4</sup>

Accordingly, the Motion to Dismiss for lack of personal jurisdiction will be granted as to all Moving Defendants. As a result of the Court's findings as to personal jurisdiction, it is unnecessary to reach the Public Entity Defendants' alternative argument as to lack of standing under the Interstate Compact Clause.<sup>5</sup>

#### II. ORDER

For these reasons, the Motion to Dismiss for lack of personal jurisdiction (**Doc. 133**) is **GRANTED** without prejudice to Plaintiffs' ability to re-file this lawsuit in an appropriate forum. In accordance with the directive in the Court's prior dismissal order (Doc. 121), further opportunity for amendment will not be afforded. IT IS FURTHER ORDERED that Plaintiffs shall have until **July 10, 2024**, to show cause why this action should not be dismissed against the Foreign Defendants (the only remaining Defendants) for failure to serve.

<sup>&</sup>lt;sup>4</sup> Although the Court declines to engage in a detailed statutory analysis, it agrees with the Moving Defendants' well-reasoned argument that Plaintiffs' allegations are "an ill fit for Pennsylvania's long-arm statute." *See* Defs.' Reply Br. (Doc. 136) at 8-11.

<sup>&</sup>lt;sup>5</sup> To the extent Plaintiffs further argue that Defendants Wilcox, Hopkin, Banikazemi, and Mauer intentionally waived jurisdiction in this case because they stated publicly in a July 2023 publication available to the public during this litigation that "the Fabry Registry complies with all applicable national privacy regulations and other regional and local laws," the Court rejects that argument as meritless for the well-articulated reasons set forth in Defendants' Brief. *See* 2d Am. Compl. ¶¶ 54-64; Defs. Br, Supp. at 22-25; Pl. Br. Opp. at 35.

IT IS SO ORDERED.

June 30, 2024 s/Cathy Bissoon

Cathy Bissoon United States District Judge

cc (via ECF email notification):

All Counsel of Record